K113443

TOTOKU

DEC 2 3 2011

510(k) SUMMARY

Submitted Information:	TOTOKU ELECTRIC CO., LTD. 300 Oya, Ueda Nagano 386-0192 Japan
Contact Person:	Tsukasa Tashiro, General Manager Email: tasirot@totoku.co.jp Tel: +81.258.24.6611 Fax: +81.258.24.6617
Date Prepared:	November 18, 2011
Device Name:	21.3 inch (54 cm) Monochrome LCD Monitor MS23i2 (ML21023)
Common Name:	MS23i2, ML21023
Classification Name:	Class II (Part 892 Radiology Devices Sec. 892.2050 Picture Archiving and Communication System)
Predicate Device:	21.3 inch (54 cm) Monochrome LCD Monitor MS21i2 (MDL2127A) (K081945)
Device Description:	MS23i2 (ML21023) is a 21.3-inch (54 cm) Monochrome LCD monitor whose display resolution is 1200 x 1600 (landscape), 1600 x 1200 (portrait) supporting DVI (digital visual interface) and Display Port.
Intended Use:	21.3 inch (54 cm) Monochrome 2M pixel LCD Monitor, MS23i2 (ML21023) is intended to be used in displaying and viewing medical images for diagnosis by trained medical practitioners. It is not meant to be used for digital mammography.
Substantial Equivalence:	MS23i2 (ML21023) shares the same characteristics with our predicate device MS21i2 (K081945) except for the main board and power supply.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

DEC 23 2011

Mr. Tsukasa Tashiro
General Manager
TOTOKU Electric Co., Ltd.
300 Oya
386-0192 UEDA NAGANO
JAPAN

Re: K113443
Trade/Device Name: 21.3 inch (54cm) Monochrome LCD Monitor MS23i2 (ML21023)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 18, 2011
Received: November 21, 2011

Dear Mr. Tashiro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: ~~Not known~~ K113443

Device Name: 21.3 inch (54 cm) Monochrome LCD Monitor MS23i2 (ML21023)

Indications for Use:

21.3 inch (54 cm) Monochrome 2M pixel LCD Monitor MS23i2 (ML21023) is intended to be used in displaying and viewing medical images for diagnosis by trained Medical practitioners. It is not meant to be used in digital mammography.

Prescription Use ✔ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113443

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Intelligent Devices and Solutions Division
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